COUNTY OF SAN BERNARDINO STANDARD PRACTICE	NO 8-3.20	Issued: 4/03
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	BY K Harris, Ph D	Effective 7/97
DEPARTMENT BEHAVIORAL HEALTH	APPROVED	
SUBJECT RESEARCH POLICY	Rudy Lopez, Director	

I. Purpose

A. To inform staff and prospective researchers about the procedures by which research proposals are evaluated

B. To set basic standards for researchers who propose to use Department resources or client data.

II. Policy

A. The Director of the Department of Behavioral Health, or designee, will approve all research, needs assessments, grant applications, and similar studies performed within the Department.

B. The Research Review Committee (RRC) is formed to advise the Director about the viability and potential benefits of research proposed within and to the Department.

III. Procedures

A. Overview

1. Projects Requiring Review and Approval. The Research Review Committee (RRC) will review all research proposals, grant application requests, and program evaluation projects, except for those that are deemed to be routine business process by the Chief of Research and Evaluation.
2. Risk-Benefit Analysis. The Committee will advise the Director regarding the feasibility and the potential risks and benefits of the proposed research. Recommendations may be for approval, revision and resubmission, or disapproval of the research proposal.
3. Time Lines. Applicants should be aware that the initial phase of the committee review process typically requires four to six weeks, after which another few weeks may be required for the applicant to address committee concerns or recommendations, and to obtain the necessary approvals from Program Managers, Deputy Directors and Director.
4. Time Limits. All projects must be completed within a year of the Director's approval signature. In special circumstances, the researcher may request additional time from the Committee via an explanatory letter.
5. Special Advisory. Graduate students who on a tight schedule are strongly advised to begin the application process early.

B. The Application Process

1. Obtaining and Submitting Application Packet. Prospective researchers should obtain an application packet from the RRC secretary. The submitted application must be in the following order:
   a. Cover Letter [1 page]
   b. Application Face Sheet (RRC-01) [1 page]
   c. Resources, Risks and Support Form (RRC-02) [1 page]

d. Statement of Agreement (RRC-03) [1 page]
e. Review and Approval Form (RRC-04) [1 page]
f. Table of Contents (RRC-05) [1 page]
g. Research Plan [typically 5 to 20 pages]
    i. Specific Aims
    ii. Background and Literature Review
    iii. Research Design and Methods
    iv. Protection of Human Subjects
    v. Special Protection for Children
    vi. Data Security Plan
    vii. References (for Literature section)
h. Attachments (Will be specific to each project)
    i. Statement of Support and Approval from Advisor (if applicable)
    ii. Sample Consent Form (commonly the standard DBH form)
    iii. Chart review tool
    iv. Data collection form
i. Surveys and instruments (include 7 copies of copyrighted instruments)

2. Incomplete packets. If incomplete, application packets will be returned to the applicant without consideration; applications may be resubmitted when complete.
3. Review Meeting. Once the completed packet is received, the RRC secretary will log its receipt and notify the Chair of the RRC. After the Chair reviews the application for completeness, the secretary will prepare and distribute photocopies of the packet to RRC members and schedule a meeting for discussion of the proposal. The committee's decision will be documented.
4. Applicant Notification. The applicant notified within two weeks of the discussion meeting. The applicant may respond to any committee concerns in writing or by email. Once the committee is satisfied that its concerns have been adequately addressed, the Chair will sign the Research Review and Approval form and return it to the applicant.
5. Obtaining Approvals. Upon receipt of the signed Review and Approval form from the committee, the applicant must obtain approvals from the Program Managers and Deputies over the sites and programs that will be affected. Following this, the applicant should return the Review and Approval form to the RCC secretary, who will forward it, along with the application packet, to the Director or designee for final authorization.
6. Appeals. If the RRC, a Program Manager, or a Deputy disapproves the application, an applicant may file an appeal with the Director. The Director's decision will be final.

C. Additional Procedures for Students.

1. All Students. If the applicant is a graduate student, the thesis or dissertation advisor or major professor must sign the application and provide a letter [RRC-10] on school letterhead to the RRC Chair stating that the research proposal represents a bona fide thesis or dissertation approved by the college or university. Applications for undergraduate or non-thesis/non-dissertation research must be accompanied by a letter [RRC-10] from the course professor stating that it is for a school-sponsored class project, that the professor has reviewed it, and that it meets the standards of quality for the university.

2. Psychology Interns. For psychology interns who are doing a non-thesis research project as part of their County Internship program, recommendation for approval to the Director will come jointly from the Psychology Training coordinator and the Research Review Chair. Committee recommendation is not necessary if there is to be no contact between the intern and clients for research purposes. The intern, however, must obtain approvals from the appropriate Program Manager and Deputy Director prior to seeking the approval of the Director.

D. Common Reasons for Delays in the Application Process.
   1. The research design is not fully explained or is inappropriate for the project, or the research questions do not arise from the literature review provided.
   2. Inappropriate or unexplained statistical procedures are specified.
   3. The experimental procedure will not answer the questions posed or clarify the status of the hypotheses stated.
   4. The application does not contain all tests, forms, and/or surveys that will be used with subjects or for data collection.
   5. A researcher-generated subject consent form is submitted that does not contain necessary information (see DBH's Consent Form).
   6. Experimental hypotheses are not clearly stated or are illogical, inconsistent, or contrary to the literature review.
   7. The applicant misestimates how much time will be required to obtain approval signatures from Program Managers.
   8. Post-research follow-up for clients who may be negatively impacted by their research participation is not proposed or covered in the design.
   9. The relevance or potential value of the research to clients, the Department, or the profession is unspecified, unclear, or unlikely.

IV. The Research Review Committee

A. Function. This committee will serve as both the Department's **Human Subjects Committee** and a research quality assurance body.

B. Membership. The Committee will consist of at least six members. The preferred composition is a psychiatrist, a psychologist, a psychiatric social worker, an administrative representative, a statistician, and the Chief of Research and Evaluation. The latter functions as the Chair of the Committee.

C. Meetings. Meetings are held as often as necessary to review applications in a timely manner. Discussion of research applications and projects may also be conducted by email or teleconferencing.

D. Review Standards. Projects are reviewed to insure that patients are protected from exploitation and to determine that some benefit is likely to result from expenditure of patient and/or staff resources. Research that clearly benefits DBH, or reasonably has the potential to benefit, will be given priority. Research that contributes to the scientific knowledge base in general will also be considered, depending on department resources.

E. Procedures. Recommendations for approval of projects require an affirmative vote by two-thirds of the members. Committee members who have personal interest in a research project shall refrain from voting so as to avoid the appearance of conflict of interest. In those instances, the number of members required for approval will be reduced by one.

F. Appointments. As vacancies occur, committee members will recommend prospective new members to the Director or designee, who will make appointments.

G. Leaves of Absence. If a permanent member takes a leave of absence, his or her discipline coordinator shall appoint a temporary replacement. Leaves of absence may not extend past one year.

H. Lack of Participation. Should a member fail to attend three consecutive meetings without prior arrangement or election for leave of absence, the committee shall nominate a replacement in accordance with section IV.E, above.

I. Research Archives. The RCC will oversee a research archive within the department. The library materials are intended to provide a source of specialized information for DBH staff, aid in the attempt to establish best practices, stimulate ideas for further research, and help avoid duplication of research effort. The archive will contain:

1. Copies of thesis and dissertations submitted as part of the degree requirements.
2. Copies of class papers and reports.
3. Copies of manuscripts sent to professional journals for publication.
4. Copies of tables of contents from books that incorporate findings of projects performed in the department.
5. Abstracts or copies of papers delivered at professional meetings.

V. Special Rules

A. Clients as Research Participants

1. Client Rights. All research projects shall be conducted with the welfare and rights of the subjects in mind, particularly if they are clients. Researchers must adhere strictly to the ethical guidelines as specified in the Ethical Principles in the Conduct of Research with Human Participants (American Psychological Association). The burden is placed upon the researcher to assure the Committee that ethical guidelines are being followed.
2. Violations. Should violations of clients' rights become known, the chair shall recommend to the Department Director that the project be immediately discontinued. The project may be later reinstated if a majority of the Committee members vote that the violations have been remedied, and the Director concurs.
3. Informed Consent. The researcher shall be responsible for carrying out the informed consent procedures as required by Title 9 of the California Administrative Code. No patient or employee shall serve as a subject without his/her consent. The patient must be told that the project is not part of his/her treatment, that participation is voluntary, and that he/she may terminate participation at any point. A document to this effect, signed by each research participant and co-signed by the researcher, must be sent to the Chair of the Research Review committee. (The researcher should also keep a copy.)
4. Confidentiality. The researcher must insure that the subject's rights of confidentiality are not violated.
5. Audio or Video Recordings. Audio or video recording requires special permission of the Committee and an additional, informed consent by the client.

B Assurance of Confidentiality. Researchers must sign the Assurance of Confidentiality as required by Article 19 of the California Mental Health Services Act.

C. Identification of Researcher. Researchers pursuing approved research must clearly identify themselves to clients when carrying out research projects with clients. Students/interns should not identify their own research projects as Departmental research. Interns and

researchers who are not DBH employees must not identify themselves as Department staff or use Department stationery.

D. Changes to Design, Scope or Implementation. Once approved, projects should be pursued in accordance with the approved design. Desired changes must be proposed to the Chair who will decide if the project must be returned to Committee for review and re-approval.

E. Oversight and Progress Reports. Research projects shall be continuously monitored to insure conformity to the approved design and to insure that the clients' rights are being protected. Researchers are assigned a contact person on the Committee to whom he/she will give a verbal (or email) progress report on a monthly basis. Failure to comply with any of the above requirements will result in summary withdrawal of project approval.

F. Final Report. Researchers must report their findings to the Research Review Committee within 60 days of project completion.

G. Handling of Data. At the conclusion of the project, copies of databases and spreadsheets containing raw data will be submitted to the Committee for archiving The researcher is responsible for the ethical and legal disposition of original data.

H. Publication. Researchers are additionally encouraged to publish or present their results. However, researchers should make it both implicitly and explicitly clear that the conclusions and opinions are those of the researcher, not necessarily those of the Department. Both DBH staff and outside researchers shall submit pre-publication versions of their manuscripts to the Research Review Committee.

I. Negative Impact. If the Committee determines that the contents of a final report or manuscript could reflect on DBH in a negative manner, it will require that a specific disclaimer be included; wording will be provided by the RRC. The Director will be apprised of any potentially harmful implications.

ATTACHMENTS

RRC-01. Application Face Sheet
RRC-02. Resources, Risks and Support Form
RRC-03. Statement of Agreement
RRC-04. Review and Approval Tracking Form
RRC-05. Table of Contents Format
RRC-06. Application Checklist
RRC-07. Informed Consent Form
RRC-09. Informational Letter for Researchers

DEPARTMENT OF BEHAVIORAL HEALTH

COUNTY OF SAN BERNARDINO
HUMAN SERVICES SYSTEM

700 E. Gilbert St • San Bernardino, CA 92415 • (909) 386-0730
Kelin S. Harris, Ph.D., Supervisor, Research and Evaluation

RUDY G. LOPEZ
Director of Behavioral Health

Researcher
Address Line 1
Address Line 2

[date]

Dear Researcher,

Thank you for your interest in doing research at the Department of Behavioral Health. Attached you will find the basic application materials. All forms are also available as Word documents (fillable forms), posted at www.psych-science.com/resapp.htm.

If you have questions after reading through this information, please feel free to contact me.

When your application packet is complete, you may mail or bring it to the following address:

Research Review Committee
700 E. Gilbert Street #6
San Bernardino, CA 92415

I may be contacted at (909) 386-0730 or by email at kharris@dbh.sbcounty.gov.

Regards,

K. S. Harris, Ph.D.
Chair, Research Review Committee

Attachments:

RRC-01 Research Application Face Sheet
RRC-02 Resources, Risks and Support Form
RRC-03 Statement of Agreement
RRC-04 Research Application Review and Approval Form
RRC-05 Table of Contents Blank
RRC-09 Informational Letter

Department of Behavioral Health
San Bernardino County, California

Research Application Face Sheet

Leave Blank – RRC Use Only
Received | Comm Date
Assigned to | Response Date.

Title of Project (max of 50 characters, including spaces) | (Assigned by RRC) Tracking No.

Project Subtitle (max of 75 characters)

Applicant		**Sponsor** (e g , graduate advisor, non-profit org, DBH, etc.)	
1 Name (last, first)		9 Name (last, first).	
2 Current Position.	3 Degree	10 Relationship to Applicant.	
4 Department, School, or Organization		11 Department, School, or Organization	
5 Address		12 Address	
6 Telephone	7 Fax	13. Telephone	14. Fax
8 Email		15. Email	

16 Client contact? ☐ Yes ☐ No
17 Involves children? ☐ Yes ☐ No
18 General Design of Study ☐ Experimental ☐ Correlational (post-hoc) ☐ Survey ☐ Case Study

19 TYPE(S) OF DATA TO BE COLLECTED

☐ Archived Records (e.g , closed charts)
☐ Active Records (e.g , open charts)
CSI Database Extracts
☐ Client Surveys or Instruments Administered by Researcher(s)
☐ Client Surveys or Instruments Administered by DBH Staff
☐ Other _____

20 DATES OF PROPOSED PROJECT PERIOD *(MM/DD/YY)*		21 DATE OF FINAL REPORT *(MM/DD/YY)*	22 ACADEMIC BASIS (if applicable)
From	To		☐ Thesis ☐ Dissertation ☐ Class Project ☐ Other _____

STATEMENT OF PROPOSAL: Concisely state both the project's broad, long-term objectives and specific aims, specifying how the project relates to the mental health field Briefly describe the research design and methods for achieving these goals This abstract is meant to serve as a succinct and accurate description of the proposed work, separate from supporting documentation If the application is approved, this description, as is, will become public information Therefore, do not include proprietary/confidential information

THIS IS A FILLABLE-FORM DOCUMENT. PLEASE USE WORD PROCESSOR OR TYPE. DO NOT EXCEED THE SPACE PROVIDED.

Resources, Risks and Support Form

ɔject Title:

DBH Resources Needed (If no resources are needed, check here ☐. If additional forms are attached, check here ☐.)

Estimated DBH Staff Hours: What type(s) of staff?
Department Equipment:
Other DBH resources:
Estimated Client Hours:

Assessment of Potential Risks (Check here if special forms or other attachments accompany this application. ☐)
Describe in detail any foreseeable risks to participants:

Describe how the researcher will mitigate these risks:

Special Considerations for Child Participants (complete this section if Box 17 on Face Sheet is checked)

Will this project involve direct contact with minors? ☐ Yes ☐ No

If "Yes", please describe in detail how parental/guardian informed consent for participation will be obtained and how the ˈildren's rights and welfare will be protected. (Check here if special consent forms or other attachments accompany this application. ☐)

Other Agency Involvement (If no other agencies are involved, please check here ☐)

If other public or private agencies, schools, or institutions will be involved in this project, please describe the nature of their involvement and your specific relationship to that agency.

Direct DBH Involvement or Support (If there is no DBH involvement, please check here ☐.)

If this project relates to or is internally supported by DBH staff or administrators, please describe the nature and involvement of these personnel.

Research & Evaluation
Department of Behavioral Health
San Bernardino County

STATEMENT OF AGREEMENT BETWEEN RESEARCH APPLICANT AND DEPARTMENT OF BEHAVIORAL HEALTH

Research applicants agree to the following conditions:

1 To conform to the ethical guidelines set forth in the APA's *Ethical Principles*, which can be obtained without cost from http //www apa org/ethics/code1992.html. (In June 2003, revised *Principles* will take effect, this is available at no charge at http //www apa org/ethics/code2002 html

2 To immediately report any client concerns or complaints to the Department's Office of Patients' Rights, and to simultaneously inform the Chair of the Research Review Committee (RRC)

3 To immediately inform the Research Review Committee of unexpected complications that may occur during the course of the research

4 To inform the RRC of any proposed changes in research design or methodology, and not to implement those changes without RRC approval

5 To maintain all DBH-derived data and information in a secure and confidential manner, protecting both information that could identify clients and data that have research value.

6 To send monthly reports of the project's progress to the Department staff assigned to monitor the research, with a copy to the Chair of the Research Review Committee (This may be done by email)

7 To provide a copy of the project's final report, thesis or dissertation to the Research Review Committee within 60 days of project completion In the event the project is terminated before completion, an explanatory report must be made to the Committee within 30 days of project termination.

8 To provide copies of all raw data, including data tables and spreadsheets kept in electronic format, to the Chair of the Committee, within 60 days of project completion or 30 days of termination, as applicable

9 After conclusion or termination of the project, to securely preserve and/or destroy all DBH-derived data and information in accordance with ethical and legal guidelines.

,PECIFIC ASSURANCE OF CONFIDENTIALITY

"As a condition of doing research involving persons who have received services from the Department of Behavioral Health, San Bernardino County, California, I agree not to divulge any information obtained in the course of such research to unauthorized persons and not to publish or otherwise make public any information regarding persons who have received services in a way that the person who received services is identifiable I understand that video and/or audio recording of clients requires special committee approval and signed consent to that effect by the client I recognize that unauthorized release of confidential information may make me subject to civil action under provisions of California's Welfare and Institutions Code."

I agree to abide by the conditions set forth above, and understand that failure to comply may result in the termination of my project, notification of my sponsoring agency or school, and referral to ethics committees and legal authorities, as appropriate.

Title of Research Proposal:

Estimated Completion Date:

_____ _____

Signature of Researcher Date

DBH Research Application
eview and Approval Tracking Form

Project Title:

Researcher: Tracking No.

Brief Description

Research Review Committee Findings

Chair	*Date*	*Signature*	*Recommendation*
Keith S Harris, Ph.D.			☐ Approval ☐ Disapproval

COMMITTEE FINDINGS AND COMMENTS

Regional Managers	*Date*	*Signature*	*Recommendation*
Terri Franklin, PM-II			☐ Approval ☐ Disapproval
Ralph Ortiz, PM-II			☐ Approval ☐ Disapproval
David Denkers, PM-II			☐ Approval ☐ Disapproval
Rita Osborne, PM-II			☐ Approval ☐ Disapproval

Deputies	*Date*	*Signature*	*Recommendation*
Terry Kramer, Dep. Dir.			☐ Approval ☐ Disapproval
Joyce Lewis, Dep. Dir			☐ Approval ☐ Disapproval

Authorization to perform the research specified in Research Application

Approving Authority	*Date*	*Signature*	*Determination*
			☐ Approved ☐ Disapproved

DBH RESEARCH PROPOSAL/ APPLICATION

Title of Project

Researcher

TABLE OF CONTENTS

Additional Information

Title of Project

Researcher

Application Submission Checklist

Because DBH receives many requests for data, access to clients, and research support, a structured approach to handling these requests has been developed. To ensure your application receives prompt, careful attention, please use and submit this checklist with your application packet.

	Yes	N/A
1. If you are a student, your application packet includes a letter from your advisor or instructor clearly indicating that your proposed research (A) has been reviewed and (B) meets the research standards of your university.	☐	☐
2. Your proposal specifies your research design and shows why it is the appropriate design for this kind of research.	☐	☐
3. Your literature review is no longer than necessary to show that the research you propose is (A) important (B) derives from previous research activities, and (C) will likely contribute new knowledge to the field.	☐	☐
4. If your design requires statistical procedures, you have consulted with people knowledgeable in this area to ensure that you have chosen the right statistic.	☐	☐
5. If you are using a research hypothesis, it is clearly stated.	☐	☐
6. You have already consulted with DBH staff at the sites you are interested in using in your research.	☐	☐
7. You have built enough time into your research design that you will not likely run into serious time pressures due to the lengthy review and authorization processes at DBH.	☐	☐
8. If your research will involve direct contact with clients, you have prepared and attached a comprehensive *Consent to Participate* form that satisfies legal and ethical requirements.	☐	☐
9. You have carefully considered potential risk factors and included in your application packet detailed information about how these will be managed.	☐	☐
10.		
11.		
12.		
13.		
14.		
15.		

Documentation of Informed Consent

Statement of Voluntary Participation for Clients

It has been fully explained to me that participation in this study is not required as part of my treatment in the department. I am taking part in this study of my own free will. I understand that I can refuse to participate now or at any time during the study, without consequence or effect on my services here. I understand that the information obtained in this study is confidential and that my rights as a participant will be fully protected as specified in the Welfare and Institutions Code and as required by the Ethical Principles of the American Psychological Association.

Signature _____

Printed Name _____ Date_____

(If participant is a child, parent's signature and printed name must be completed below)

Parent's Signature _____

Parent's Printed Name _____ Date_____

Statement of Voluntary Participation for Employees

It has been fully explained to me that participation in this study is not required as condition of my employment in the department. I am taking part in this study of my own free will. I understand that I can refuse to participate now or at any time during the study, without consequence or effect on my employment. I understand that the information obtained in this study is confidential and that my rights as a participant will be fully protected as specified in the Welfare and Institutions Code and as required by the Ethical Principles of the American Psychological Association.

Signature _____

Printed Name _____ Date_____

Researcher Acknowledgement

Signature _____

Printed Name _____ Date_____

Note: The original of this form must be submitted to the Chair of the Research Review Committee for inclusion in that investigator's file.

DOING RESEARCH AT DBH

Research & Evaluation
Department of Behavioral Health
San Bernardino County

Informational Letter RRC-20030118

Detailed information may be found in DBH-SPM 8-1.30, *Research Policy and Procedures.*

Overview of Application and Research Process

1. Researcher submits Application Packet to the Secretary of the RRC.
2. RRC meets and considers project.
3. Applicant is informed of the results of the RRC review.
4. If research is approved as submitted, the chair of the RRC signs the R&A Form and returns it to applicant (skip to step 7).
5 If research plan is not approved, applicant may revise and resubmit. (NOTE: Resubmissions must be complete packets unless the committee specifically requests otherwise.)
6. RRC will reconsider revised application. If approved, Chair will sign R&A Form and return to applicant. If still not acceptable to the committee, applicant may revise project again or file an appeal with the Director of Behavioral Health.
7. Once the RRC approves the project, or if the Director authorizes the project on appeal, applicant must obtain approval signatures from the program managers of the regions from which participants will be drawn, from the Deputy or Deputies over those regions, and from the Director or his designee (if not signed earlier).
8. For the duration of the project, the researcher must submit a monthly project update to the Department contact assigned to that project, with a copy to the Chair of the RCC.
9. At the conclusion of the project, researcher must provide the Committee with a copy of the research (thesis, dissertation, paper, manuscript, etc.) and copies of databases and spreadsheets containing raw data.

Contents of Application Packet

1. Cover Letter [1 page]
2. Application Face Sheet (RRC-01) [1 page]
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4 Statement of Agreement (RRC-03) [1 page]
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6. Table of Contents (RRC-05) [1 page]
7 Research Plan [typically 5 to 20 pages]
    a. Specific Aims
    b. Background and Literature Review
    c. Research Design and Methods
    d. Protection of Human Subjects
    e. Special Protection for Children
    f. Project Schedule
    g. Data Security Plan
    h. References (for Literature section)
8. Attachments (will be specific to each project)
    a Statement of Support and Approval from Advisor (if applicable)
    b. Sample Consent Form
    c. Chart review tool
    d. Data collection form
    e. Surveys and instruments

Department of Behavioral Health
San Bernardino County, California

R&E Project Face Sheet

Planned Start Date:

Primary Staff:

1 Title of Project (max of 50 characters, including spaces)
Children Length of Stay

Project No. **1029**

2. Project Subtitle (max of 75 characters)

3 Client contact? ☐ Yes ☒ No

4 Involves children? ☒ Yes ☐ No

5 General Design of Study ☐ Experimental ☐ Correlational (post-hoc) ☐ Survey ☐ Program Review

6 TYPE(S) OF DATA TO BE COLLECTED

☐ Archived Records (e.g , closed charts)
☐ Active Records (e g , open charts)
☐ CSI Database Extracts
☐ Client Surveys or Instruments Administered by Researcher(s)
☐ Client Surveys or Instruments Administered by DBH Staff
☐ Other _____

7 DATES OF PROPOSED PROJECT PERIOD *(MM/DD/YY)*
From | To

8 DATE OF FINAL REPORT *(MM/DD/YY)*

9. TYPE OF FINAL PRODUCT
☐ Report ☐ Presentation ☐ Database
☐ Other _____

PROJECT SUMMARY: